Complete Summary

GUIDELINE TITLE

Guidelines regarding HIV and other bloodborne pathogens in vascular/interventional radiology.

BIBLIOGRAPHIC SOURCE(S)

Hansen ME, Bakal CW, Dixon GD, Eschelman DJ, Horton KM, Katz M, Olcott EW, Sacks D. Guidelines regarding HIV and other bloodborne pathogens in vascular/interventional radiology. J Vasc Interv Radiol 2003 Sep;14(9 Pt 2):S375-84. [61 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Hansen ME, SCVIR Technology Assessment Committee, Bakal CW, Dixon GD, Eschelman DJ, Horton KM, Katz M, Olcott EW, Sacks D. Guidelines regarding HIV and other bloodborne pathogens in vascular/interventional radiology. J Vasc Interv Radiol 1997 Jul-Aug;8(4):667-76.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Transmission of bloodborne pathogens including

- Human immunodeficiency virus (HIV)
- Hepatitis B virus
- Hepatitis C

GUIDELINE CATEGORY

Prevention
Risk Assessment

CLINICAL SPECIALTY

Preventive Medicine
Radiology

INTENDED USERS

Allied Health Personnel
Nurses
Physicians

GUIDELINE OBJECTIVE(S)

- To review current knowledge about risk of blood borne pathogen transmission during interventional radiology procedures
- To summarize exposure control regulations and recommendations as they pertain to the practice of interventional radiology and review ways that risk can be reduced
- To formulate a policy for the Society to assist its members in addressing human immunodeficiency virus (HIV)-positive physicians with local hospital boards and other regulatory bodies

TARGET POPULATION

Patients undergoing interventional radiology

INTERVENTIONS AND PRACTICES CONSIDERED

1. Testing for human immunodeficiency virus
2. Current exposure control regulations, including exposure control plans, universal precautions, personal protective equipment, hepatitis B vaccination, training in infection control, and post exposure prophylaxis and counseling.
3. Minimization of risk of pathogen transmission with:
    - Barrier devices and personal protective equipment
    - Procedural precautions
    - Equipment precautions
    - Specimen handling precautions
4. Full practice privileges versus restrictions for human immunodeficiency virus (HIV)-infected physicians

MAJOR OUTCOMES CONSIDERED

- Pathogen transmission from patient to health care worker
- Pathogen transmission from health care worker to patient

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This document was developed by the Bloodborne Pathogen Subcommittee of the Society of Interventional Radiology (SIR) with assistance from the Technology Assessment Committee. Consensus on its major provisions was obtained by using a modified Delphi polling method; three rounds of polling were conducted and consensus was obtained on all items. The polling questions and related data are on file in the SIR office.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline recommendations are sent to the Executive Council for preliminary review, and to the Society of Interventional Radiology (SIR) Membership for review and comment. Membership comments are tabulated and distributed to the SIR Standards of Practice Committee. The Committee discusses the comments and edits the recommendations if warranted. The SIR Membership may be re-surveyed, if necessary. The recommendations are subsequently sent to the Executive Council for final review, comments, and approval.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Procedure Safety: Recommendations and Regulations

Current Exposure Control Regulations

In 1992, the Bloodborne Pathogens Standard developed by the Occupational Safety and Health Administration (OSHA) was enacted into law. Failure to comply is a federal offense. The most important features of the Standard are summarized below. More detailed information can be found in a recent review by Decker or in the complete text of the Standard and its supporting documents.

1. Materials considered infectious/potentially infectious include blood; semen; cerebrospinal, vaginal, synovial, pleural, pericardial, peritoneal, or amniotic fluid; any fluid that is either contaminated with blood, mixed with another potentially infectious fluid, or of uncertain origin; and saliva in dental procedures. Stool is included only if visible blood is present. Urine is generally not included either, but it should be considered potentially infectious if the urinary tract has sustained trauma or been instrumented. All such materials other than blood are grouped under the term "other potentially infectious materials," or OPIM.
2. Occupational exposure is defined as parenteral, skin, or mucous membrane (including conjunctival) contact with blood or OPIM that may be reasonably anticipated to result from the performance of a health care worker's duties. This includes contact that is prevented by use of protective equipment, such as gloves, gowns, and face and eye protection (goggles, masks, and shields).
3. An exposure control plan must be developed by every employer of at least one worker whose duties put him/her at risk for occupational exposure. This plan must be reviewed with employees and contain a schedule for meeting

the various requirements of the Standard regarding hepatitis B vaccination, training, record-keeping, post-exposure treatment, and so on. The plan must detail measures that the employer will take to reduce exposure risks.

4. The Standard mandates adherence to universal precautions, as well as certain specific engineering and work practice controls. Two-handed recapping of contaminated sharps instruments is strictly prohibited, as is bending or breaking of contaminated needles. Contaminated sharps must be placed in appropriate containers immediately after use. Handwashing facilities must be readily accessible; hands must be washed every time gloves are removed or changed. Eating, drinking, handling of contact lenses, and use of cosmetics are prohibited in work areas where exposure may occur. Specimens must be placed in sealed, leakproof containers that are red or bear the label "biohazard." Appropriate personal protective equipment must be provided for employees at risk, and cleaned, repaired, or replaced as needed.
5. Employers must provide employees who are at risk for occupational exposure with hepatitis B vaccine free of charge. Vaccination may be refused, but the employee must sign a form indicating that it was offered and declined. Training in infection control must be provided within 10 days of an employee being hired and at least once annually thereafter, and must be documented. The Standard details certain elements that must be included. Records of this training must be kept for 3 years. Records relating to hepatitis vaccination and postexposure follow-up must be kept for the duration of employment, plus 30 years. Records must be made available to OSHA and to the employee.
6. Employers must provide post-exposure prophylaxis and counseling. Blood from the source of the exposure must be obtained and tested for human immunodeficiency virus (HIV) and hepatitis B virus (HBV) unless the person is already known to be infected or consent, if required, is refused, in conjunction with individual state law. Although hepatitis C virus (HCV) is not specifically mentioned in the OSHA Standard, testing for infection with this virus may also be indicated. Refusal must be documented. Results of testing must be provided to the exposed employee, who is to be informed of applicable laws concerning disclosure of the source's identity. The employee also may have blood collected for testing, or to be stored for at least 90 days while the employee considers whether to have testing done. The employer is to be told only that the exposed worker has been informed of the evaluation's results and of any further evaluation or treatment that is needed. The actual results of the evaluation and all other findings are considered confidential. All records pertaining to an exposure incident must be kept for the duration of employment, plus 30 years. Although not discussed explicitly in the Standard, chemoprophylaxis is warranted after high-risk exposure to HIV; more information and recommended regimens may be found in a recent report from the U.S. Public Health Service.

Minimizing the Risk of Bloodborne Pathogen Transmission in Interventional Radiology

The Society of Interventional Radiology (SIR) endorses the precautions delineated by OSHA and the U.S. Centers for Disease Control and Prevention (CDC) and urge members to adhere to these guidelines. These general recommendations, which include adherence to universal precautions, use of appropriate protective equipment, and safe handling practices for sharps, can be expanded to yield techniques that more specifically address the practice of interventional radiology,

as has been done for surgical practice. Accordingly, SIR proposes four categories of specific precautions: 1) barrier devices and personal protective equipment; 2) performance of procedures; 3) equipment; and 4) handling of specimens.

Barrier Devices and Personal Protective Equipment

Standard precautions for all interventional radiology procedures should include: 1) handwashing with a germicidal and virucidal agent before and after each case (immediately after removing gloves); and 2) wearing appropriate protective clothing, including gloves, transparent face shield or a mask plus goggles with side protectors, and coverage of all areas of nonintact skin with a fluid-impermeable material.

Because occult perforations in surgical gloves increase with time worn, it may be prudent to change gloves after 90 minutes of wear whether a perforation is apparent or not. Double-gloving is recommended when breaks in the skin are noted, and some individuals may elect to double-glove routinely. When there is a risk of splashing of blood or body fluids, such as when removing a vascular catheter at the end of a procedure, eye and face protection should be worn, as well as gloves. Wearing a gown is also recommended if there are breaks in the skin of the arms.

When there is a reasonable risk of exposure to blood or bloody fluid during any vascular or interventional procedure, the following additional protective clothing are recommended in addition to the items listed previously: surgical "scrub" attire; shoes worn only for performing procedures; fluid-impermeable gown; shoe covers or gaiters to cover lower legs and feet; and hair covering.

Generally, simple peripheral intravenous access procedures (such as starting intravenous lines or phlebotomy) would not fall into this category. Gloves and a face shield are adequate for these procedures in most cases. Whenever transfusion equipment or blood products are handled, eye protection and gloves should be worn. Contaminated work surfaces must be cleansed and disinfected promptly after contamination is noted, and at the end of each procedure whether visibly soiled or not.

Procedural Precautions

1. Recapping of needles or resheathing of scalpel blades by hand is to be avoided whenever possible. If this is not possible, one of the following methods must be used: a one-handed technique wherein the cap is "scooped up" with the point of the exposed sharp instrument, or a two-handed technique wherein the cap is held with a clamp or other mechanical device, not the operator's fingers.

   When needles must be removed from syringes or exchanged, this too should be done by using a clamp or other mechanical device, rather than one's fingers. Use of disposable scalpels rather than reusable metal handles is strongly recommended.

2. Immediately after being used, all disposable sharp instruments that may be reused during a given procedure should be placed into stable plastic devices designed for use on procedure trays. These holding devices should be placed in an area of the tray where they will not be in the way and will not be readily knocked or tipped over. All members of the operating team must be aware of the nature and location of the designated container. Disposable sharp instruments that will not be reused during a given procedure should be disposed of in appropriate containers immediately after use. Sharps containers must be of adequate dimensions to contain all sharp instruments used in a procedure completely, with no portion of the instrument protruding from the opening of the container. Sharp instruments should not be bent to force them to fit into a container that is not large enough to accommodate them.
3. All nondisposable sharp instruments must be placed into designated containers immediately after use. These containers must be of adequate dimensions to contain the instruments completely, as described under section 2 (discussed previously). All members of the operating team must be aware of the nature and location of the designated container.
4. Members of the operating team should communicate verbally regarding the use and location of all sharp instruments.
5. Sharp instruments should not be handed directly from one team member to another. Rather, the "no touch" method should be used, in which the instrument is set down onto a stable surface by one team member, who then withdraws his/her hand before the instrument is picked up by a second team member.
6. Suturing should be performed only by using needle holders, never by holding or grasping the needle in one's fingers. Palpation to locate or guide the needle tip should never be done. Similarly, whenever a sharp instrument is in use, the operator should remove his/her nondominant hand from the field unless patient safety would be compromised by doing so.
7. Disposal containers for sharp instruments must be readily available, conveniently located, and labeled according to OSHA regulations. Containers must be replaced before they are three-quarters full, or whenever items protrude from the opening.
8. Adequate lighting in procedure rooms is essential. For dedicated angiointerventional rooms, tableside control of room lighting is recommended. This may be accomplished via a light switch or by interconnection of the fluoroscopy controls and the room lighting.
9. Technologists or other personnel who clean procedure trays should use long-handled forceps or clamps to remove sharp instruments. Gloves should be worn in all cases, and splash protection (gown, face shield, or mask plus goggles) may be needed also.
10. If a member of the operating team sustains a sharps injury, the instrument responsible must be removed from the procedure field immediately, without being reused on the patient. Any additional pieces of equipment that have come in contact with the injured health care worker's blood, such as guide wires, catheters, gauze pads, and so on, must be discarded immediately as well. The exposed individual shall follow the procedure for reporting and treatment of exposure incidents that has been established at that facility.

Equipment Precautions

1. Closed flush and waste containment systems should be used for angiography.
2. Drainage of large fluid collections should be done with use of closed drainage sets.
3. Self-sheathing or needleless intravenous systems should be used whenever possible.
4. Glass syringes should not be used unless plastic syringes are not suitable.
5. Luer-lock fittings are preferred over the Luer-slip type for all syringes, connecting tubing, drainage systems, and the like.
6. "Bloodless" puncture systems for arterial and/or venous access are widely available and may be used at the discretion of the operator.
7. Resuscitation bag/mask sets should be available in all patient care areas, including procedure rooms.
8. Plastic containers or other stable devices designed to contain sharp instruments on procedure trays while maintaining their sterility should be used whenever possible.
9. Glass containers (such as contrast media bottles) should be disposed of in sharps containers, rather than in waste bags, to reduce the risk of injury to housekeeping personnel from breakable materials in infectious waste bags. Removal of the metal caps from contrast or medication vials should be done with a hemostat or other instrument to avoid injury, and the metal tops should then be placed in a sharps disposal container.

Specimen Handling Precautions

1. Gloves must be worn at all times when handling specimens.
2. Specimens must be placed in clearly marked, sealed containers, which are then transported inside a second sealed container (such as a bag) that is labeled "biohazard."
3. Facial splash protection (face shield, or mask and goggles) must be worn when fluid samples are injected into containers or poured from containers.

Practice Guidelines for HIV-Positive Physicians

All available evidence suggests that the risk of bloodborne pathogen transmission from health care workers to patients during interventional radiology procedures is minimal, and thus SIR believes there is no reason to restrict the practice of infected individuals except in unusual cases. A policy that allows some flexibility is essential, both to ensure patient safety and to protect the rights of practitioners. Practice restrictions, if needed, should be based on a case-by-case review by a local review panel as described in the guideline document.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

Information about the risk of bloodborne pathogen transmission during procedures in interventional radiology is limited. The guideline developers took what is currently known about the level of risk in interventional radiology and compared that to what is known for surgery, which is probably the medical specialty with the greatest risk.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The use of appropriate precautions and protective equipment and compliance with exposure control regulations can reduce the risk of pathogen transmission from patient to health care worker and from health care worker to patient.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The policy set out in the guideline document is not meant to be immutable, but it will be reviewed and updated as more information becomes known.
- The clinical practice guidelines of the Society of Interventional Radiology (SIR) attempt to define practice principles that generally should assist in producing high quality patient care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The final version of the guideline, as approved by the Executive Council, is sent to the Journal of Vascular and Interventional Radiology for publication, American Medical Association practice parameters CD-ROM, Radiological Society of North America (RSNA) Internet Directory, and American College of Radiology. The document is placed in the Society of Interventional Radiology (SIR) Standards

Packet (with revised table of contents), and disseminated to subscribers listed in the Standards of Practice Committee Database.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Efficiency
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Hansen ME, Bakal CW, Dixon GD, Eschelman DJ, Horton KM, Katz M, Olcott EW, Sacks D. Guidelines regarding HIV and other bloodborne pathogens in vascular/interventional radiology. J Vasc Interv Radiol 2003 Sep;14(9 Pt 2):S375-84. [61 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Jul-Aug (revised 2003 Sep)

GUIDELINE DEVELOPER(S)

Society of Interventional Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Interventional Radiology

GUIDELINE COMMITTEE

HIV/Bloodborne Pathogens Subcommittee with the assistance from the Technology Assessment Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

HIV/Bloodborne Pathogens Subcommittee Members: Margaret E. Hansen, MD, Chair; Curtis W. Bakal, MD, MPH; G. David Dixon, MD; David J. Eschelman, MD; Keith M. Horton, MD; Michael Katz, MD; Eric W. Olcott, MD; David Sacks, MD

Technology Assessment Committee Members: Gary J. Becker, MD, Dana R. Burke, MD, Patricia E. Cole, MD, Michael D. Dake, MD, Richard J. Gray, MD, Ziv J. Haskal, MD, Robert W. Holden, MD, Lindsay S. Machan, MD, Nilesh H. Patel, MD, and Richard Shlansky-Goldberg, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Hansen ME, SCVIR Technology Assessment Committee, Bakal CW, Dixon GD, Eschelman DJ, Horton KM, Katz M, Olcott EW, Sacks D. Guidelines regarding HIV and other bloodborne pathogens in vascular/interventional radiology. J Vasc Interv Radiol 1997 Jul-Aug;8(4):667-76.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Society of Interventional Radiology Web site.

Print copies: Available from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, Virginia 22030.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Sacks D, McClenny TE, Cardella JF, Lewis CA. Society of Interventional Radiology clinical practice guidelines. J Vasc Interv Radiol 2003 14:S199-S202.

Electronic copies: Available in Portable Document Format (PDF) from the Society of Interventional Radiology Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 14, 2000. It verified by the guideline developer as of July 24, 2000. This NGC summary was updated by ECRI

on January 18, 2005. The updated information was verified by the guideline developer on January 21, 2005.

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